

Application No.: 10/664,454
Amendment and Response dated April 3, 2006
Reply to Office Action of December 1, 2005
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Remarks

The application has been amended. These amendments do not introduce new matter. In particular, claims 1 and 27 have been amended to replace the term "about" with "adjacent", and to further define the pocket containing the bioactive agent. Support for these amendments can be found, for example, in paragraphs [0033] and [0034] and in the figures of the present application. It is noted that the term "about" was used interchangeably with the term "adjacent" in the specification (see, for example, paragraph [0033]). Previously withdrawn claims 28-47 have now been canceled, without prejudice to pursuing them in one or more divisional or continuation applications.

Claim Rejections Under 35 U.S.C. §102(e)

In the Final Office Action, the Examiner has maintained the rejection of claims 1-22 and 27 under 35 U.S.C. §102(e), as allegedly being anticipated by U.S. Patent Application No. 2003/0074049 (hereinafter "Hoganson"). Whilst the Examiner admits that Hoganson does not utilize the term "bonded" when referring to the first and second covers/liners shown in Fig. 2c, she goes on to state the following:

Hoganson, et al. does however state in section [0078] that the covers may be located in the interstitial spaces between the portions of sections "24". It would have been obvious to one having ordinary skill in the art that because the inner and outer covers are "between" the spaces and framework that they meet the broad term "bonded" (which is not defined by the applicant's specification).

In consideration of the claim amendments and the arguments presented herewith, the rejection of claims 1-22 and 27 is respectfully traversed.

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Amended claims 1 and 27 provides a device for delivery of bioactive agents associated therewith to a site of implantation of the device. The device includes a first polymeric liner, a second polymeric liner, and an intermediate structural member defined by solid segments and openings therebetween. The first polymeric liner is bonded to the second polymeric liner through the openings so as to form a pocket adjacent to the solid segments, the pocket being defined by the first and second liners and the solid segments. The device further includes a bioactive agent located within the pocket.

Hoganson discloses a covered stent. As recognized by the Examiner, in Fig. 2c of Hoganson, an embodiment is shown where a cover is located on the exterior of the stent framework, and a cover is located on the interior of the stent framework. However, contrary to the Examiner's assertions, the exterior and interior covers are not bonded to each other. Cited paragraph [0078] states that the cover 22, not covers, may be located in the interstitial spaces between portions or sections 24 of the framework, so as to effectively be in the middle of the stent. This is an important distinction because it suggests that a single cover 22 in the form of a single layer or a laminate of materials can be located in the interstitial spaces. However, neither Fig. 2c, nor paragraph [0078] disclose or suggest that more than one cover/liner is "between" the spaces and framework, as claimed. Moreover, while bonding is disclosed in Hoganson, it is only with respect to a single piece of a polymeric film or a polymer tube, where the film/tube may be bonded to the stent, itself or both (paragraphs [0095] and [0099]). However, there is no suggestion to bond/laminate separate polymeric liners to each other through the open portions of an intermediate stent to form pockets adjacent to the stent, as set forth in the claims.

Moreover, even if these limitations were met, which they are not, Hoganson fails to disclose or suggest drugs/bioactive agents located in a pocket, as claimed. With reference to Figs. 2-7 of the present application, independent claims 1 and 27 have been amended to clarify that pocket 26 is defined by liners 14, 16 and solid segments 24/40 of the intermediate structural member (e.g. stent). Therefore, liners 14, 16 are located outside of pocket 26. In the

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Final Office Action, the Examiner contends that she has addressed Applicant's argument that Hoganson does not disclose drugs/bioactive substances in a pocket, but Applicant does not agree. The Examiner only states that Hoganson's covers/liners have drugs within them that when fixed between the interstitial spaces of the framework, then form a "pocket" around the struts of the stent. The "openings/interstitial spaces" and the "pocket" are different elements of the present claims. Therefore, even if Hoganson's liners containing drugs were fixed between the interstitial spaces, the liners and the drugs within them would at best be located in the interstitial spaces-not in a pocket. Therefore, Hoganson's drug particles are not contained in any pocket.

Since the Hoganson reference fails to disclose or suggest bonding of the polymeric layers through open stent portions to form pockets, and also fails to disclose a bioactive agent contained in a pocket, the claims of the present invention are deemed to be patentably distinct over Hoganson.

Claim Rejections Under 35 U.S.C. §103 (a)

The Examiner further rejects claims 23-26 as being allegedly unpatentable over Hoganson, et al. in view of U.S. Patent No. 6,001,125 to Golds, et al. In particular, the Examiner uses the Golds reference for its disclosure with respect to internodal distance.

Claims 23-26 are dependent upon claim 1. As set forth above, claim 1 is patentably distinct over the primary reference. The Golds reference fails to fill the deficiencies of the primary reference. Therefore, claims 23-26 are similarly patentable.

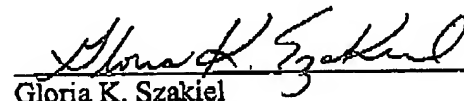
Summary

Applicant has responded in full to the present Office action. It is believed that all of the claims of the present invention are patentable over the cited references, either alone or in combination. Favorable action thereon is respectfully solicited.

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Should the Examiner have any questions or comments concerning this Response, the Examiner is respectfully invited to contact the undersigned agent at the telephone number set forth below.

Respectfully submitted,



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